



DEPARTMENT OF HEALTH AND HUMAN SERVICES

HFI-35
Food and Drug Administration
Atlanta District Office
Purged 12/1/01

60 8th Street, N.E.
Atlanta, Georgia 30309

November 20, 2000

VIA FEDERAL EXPRESS

Charles D. Smith, President
Luther L. Smith & Son, Inc.
928 S. Seashore Drive
Atlantic, NC 28511

Warning Letter

01-ATL-11

Dear Mr. Smith:

On July 17 & 18, 2000, the Food and Drug Administration (FDA) conducted an inspection of your plant located at Atlantic, North Carolina. During that inspection, our investigator documented serious deviations from the Seafood HACCP regulations (21 CFR Part 123). These deviations, some of which were previously brought to your attention, cause your fresh shrimp and scombrototoxic fish to be in violation of section 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act). You can find this Act and the seafood HACCP regulations through links in FDA's home page at www.fda.gov.

The deviations were as follows:

1. You must have a HACCP plan that lists the critical limits that must be met, in order to comply with 21 CFR 123.6(c)(3). However, your firm's HACCP plan for histamine-producing fish lists critical limits, i.e., "chill in ice bath immediately", and "store below 45 degrees F" at the receiving CCP and the cooler CCP respectively, which are not adequate to control the histamine hazard. Adequate receiving critical limits for the control histamine formation includes documentation of temperature control at or below 40 degrees F during transit or observation of an adequate amount of ice at receipt. A critical limit of 40 degrees F or below is adequate for the cooler critical control point.
2. You must implement the monitoring procedure listed in your HACCP plan, in order to comply with 21 CFR 123.6(b). However, your firm is not following the monitoring procedure of visually checking that the labeling of each case of shrimp bears a sulfite declaration at the labeling CCP, to control the sulfite hazard listed in your HACCP plan for raw shrimp.

The above deviations were previously brought to your attention in our letter dated April 18, 2000.

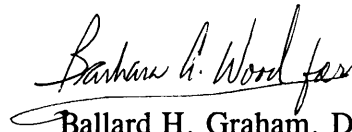
We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your operating firm.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as copies of HACCP plans, and HACCP monitoring records, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Please send your reply to Karen Y. Dodson, Compliance Officer, U.S. Food and Drug Administration, 60 Eighth Street, N.E., Atlanta, Georgia 30309. If you have questions regarding any issue in this letter, please contact Mrs. Dodson at (404) 253-1299.

Sincerely,


Ballard H. Graham, Director
Atlanta District